Safetygram

NCI-Frederick

ISM-185 LABORATORY PERSONNEL June 2003

CDC SELECT AGENTS & USDA HIGH CONSEQUENCE AGENTS

BACKGROUND

On June 12, 2002, President Bush signed the "Public Health Security and Bioterrorism Preparedness Response Act of 2002" (Public Law 107-188). The law is designed to improve the ability of the United States to prevent, prepare for, and respond to bioterrorism and other public health emergencies. Section 202(a) of the Law requires that all persons possessing biological agents or toxins deemed a threat to public health to notify the Secretary, Department of Health and Human Services (HHS). Section 213(b) of Law requires all persons possessing biological agents or toxins deemed a threat to animal or plant health and to animal or plant products notify the Secretary, United States Department of Agriculture (USDA).

HHS and the USDA published regulations detailing the requirements for facilities or entities that possess, use, or transfer select agents and toxins. The HHS regulation 42 CFR 73, the USDA regulations 9 CFR 121 and 7 CFR 331 was published in the December 13, 2002, edition of the Federal Register. The Centers for Disease Control (CDC) has been designated as the responsible agency for HHS and the Animal and Plant Health Inspection Service (APHIS) has been designated as the responsible agency for the USDA. The new USDA and HHS regulations requires that entities **possessing** biological agents that are listed as CDC select agents, CDC/USDA overlap agents or USDA high consequence animal and plant pathogens and toxins must register with CDC and/or APHIS and demonstrate compliance with specific safety and security standards for handling these agents.

In the performance of scientific research, the NCI-Frederick may have occasion to use Select Agents as defined by 42 CFR §73, or High Consequence Animal or Plant Pathogens and Toxins as defined by 9 CFR §121 and 7 CFR §331. It is the policy of the NCI-Frederick to ensure that receipt, usage; storage, shipping and disposal of this material are performed in compliance with all applicable federal and state regulations and laws.

The NCI-Frederick Institutional Biosafety Committee reviews and approves research with biologicals that is conducted or sponsored by NCI-Frederick. EHS maintains registries of projects, which use pathogens or recombinant DNA/RNA. These registries allow EHS to inform CDC or APHIS of those research projects at NCI-Frederick that will be affected by the HHS or USDA regulations. Registration of biological research protects researchers from non-compliance with applicable regulations and legitimizes their possession of regulated biological agents and toxins. This is especially critical since The USA Patriot Act of 2001, amends Section 175 of the U.S. Criminal Code to allow prosecution of individuals who knowingly possess any biological agent, toxin, or delivery system of a type or in a quantity not reasonably justified by prophylactic, preventive, bona fide research or other peaceful purpose.

REQUESTING A SELECT AGENT

An NCI-Frederick employee requesting to obtain a "Select Agent" or USDA High Consequence Animal or Plant agents (listed on the following page) as defined by the applicable regulation shall contact the NCI-Frederick Biological Safety Officer who serves as the NCI-Frederick Responsible Official. Additional requirements for that receipt, usage; storage, transfer and disposal of regulated biological agents will be discussed at that time. Additional requirements for receiving a Select Agent may include:

- X Registration of proposed work with EHS, IBC and the CDC or USDA-APHIS.
- X Inspection of laboratory facilities.
- X Review of research protocols and SOPs.
- X Method of storage and disposal of material when the work has been completed.
- X Review of training records of staff who will be involved with the project. This review will ensure proficiency of individuals working with select agents.
- X Method of securing the agent.
- X **FBI Security Risk Assessment of individuals having access to regulated agents.**

More information is available on this topic in the EHS Compliance Manual Chapter D-4 or by contacting the Biological Safety Officer at X1451

HHS Select Agents, and USDA High Consequence Livestock & Plant Pathogens or Toxins

Viruses

1. African horse sickness virus
2. African swine fever virus
3. Akabane virus
4. Avian influenza virus (highly pathogenic)
5. Blue tongue virus (exotic)
6. Camel pox virus
7. Cercopithecine herpes virus (Herpes B virus)
8. Classical swine fever virus
9. Crimean-Congo haemorrhagic fever virus
10. Eastern equine encephalitis virus
11. Ebola viruses
12. Foot and mouth disease virus
13. Goat pox virus
14. Japanese encephalitis virus
15. Lassa fever virus
16. Lumpy skin disease virus
17. Malignant catarrhal fever
18. Marburg virus
19. Menangle virus
20. Monkeypox virus
21. Newcastle disease virus (exotic)
22. Nipah and Hendra complex viruses
23. Peste des petits ruminants
24. Plum pox potyvirus
25. Rift Valley fever virus
26. Rinderpest virus
27. Sheep pox
28. South American haemorrhagic fever viruses [(Junin, Machupo, Sabia, Flexal, Guanarito)]
29. Swine vesicular disease virus
30. Tick-borne encephalitis complex (flavi) viruses [Central European Tick-borne encephalitis, Far Eastern Tick-borne encephalitis (Russian Spring and Summer encephalitis, Kyasanur Forest disease, Omsk Hemorrhagic Fever)]
31. Variola major virus (Smallpox virus) and Variola minor (Alastrim)
32. Venezuelan equine encephalitis virus
33. Vesicular stomatitis virus (exotic)

Prion

1. Bovine spongiform encephalopathy agent

Toxins

1. Abrin
2. Botulinum neurotoxins
3. *Clostridium perfringens* epsilon toxin
4. Conotoxins
5. Diacetoxyscirpenol
6. Ricin
7. Saxitoxin
8. Shigatoxin and Shiga-like ribosome inactivating proteins
9. Staphylococcal enterotoxins
10. Tetrodotoxin
11. T– 2 toxin

Bacteria

1. *Bacillus anthracis*
2. Botulinum neurotoxin producing strains of *Clostridium*
3. *Brucella abortus*
4. *Brucella melitensis*
5. *Brucella suis*
6. *Burkholderia mallei*
7. *Burkholderia pseudomallei*
8. *Coxiella burnetii*
9. *Cowdria Ruminantium* (Heartwater)
10. *Francisella tularensis*
11. *Liberobacter africanus, Liberobacter asiaticus*
12. *Mycoplasma capricolu/M.* F38/*M. mycoides capri* (contagious caprine pleuropneumonia agent)
13. *Mycoplasma mycoides mycoides* (contagious bovine pleuropneumonia agent)
14. *Ralstonia solanacearum* Race 3
15. *Rickettsia prowazekii*$^{\psi}$
16. *Rickettsia rickettsii*
17. *Xanthomonas oryzae* pv. oryzicola
18. *Xylella fastidiosa* (citrus variegated chlorosis strain)
19. *Yersinia pestis*

Fungi

1. *Coccidioides immitis*
2. *Coccidioides posadasii*
3. *Peronosclerospora philippinensis*
4. *Phakopsora pachyrhizi*
5. *Sclerophthora rayssiae var zeae*
6. *Synchytrium endobioticum*

Exemptions

The following agents or toxins are exempt if the aggregate amount under the control of a principal investigator does not, at any time, exceed:

- 0.5 mg of Botulinum neurotoxins
- 5 mg of *Staphylococcal* enterotoxins
- 100 mg of abrin, *Clostridium perfringens* epsilon toxin, conotoxin, ricin, saxitoxin, shigatoxin, shiga-like ribosome inactivating protein, and tetrodotoxin
- 1,000 mg of diacetoxyscirpenol and T-2 toxin

The following agents or toxins are also exempt:

- Any agent or toxin that is in its naturally occurring environment provided it has not been intentionally introduced, cultivated, collected, or otherwise extracted from its natural source.
- Non-viable select agent organisms or nonfunctional toxins.
- The vaccine strains of Junin virus (Candid #1), Rift Valley fever virus (MP-12), Venezuelan Equine encephalitis virus vaccine strain TC-83.
- The medical use of toxins for patient treatment is exempt.

Genetic Elements, Recombinant Nucleic Acids, and Recombinant Organisms

1. Select agent viral nucleic acids (synthetic or naturally derived, contiguous or fragmented, in host chromosomes or in expression vectors) that can encode infectious and/or replication competent forms of any of the select agent viruses.
2. Nucleic acids (synthetic or naturally derived) that encode for the functional form(s) of any of the listed toxins if the nucleic acids: a) are in a vector or host chromosome; b) can be expressed *in vivo* or *in vitro*; or c) are in a vector or host chromosome and can be expressed *in vivo* or *in vitro*.
3. Listed viruses, bacteria, fungi, and toxins that have been genetically modified.

Other Restrictions

1. Experiments utilizing recombinant DNA that involve the deliberate transfer of a drug resistance trait to the listed agents that are not known to acquire the trait naturally, if such acquisition could compromise the use of the drug to control disease agents in humans, veterinary medicine, or agriculture.
2. Experiments involving the deliberate formation of recombinant DNA containing genes for the biosynthesis of listed toxins lethal for vertebrates at an LD50 < 100 ng/kg body weight.